Remarks

Claim 1, 2, and 4-6 are currently pending in the application. Claim 1 is amended.

1. Claim Rejections - 35 USC §112, second paragraph

Claim 6 stands rejected under 35 USC §112, second paragraph as being indefinite. Specifically, the Action asserts that the phrase "multiplicity of stains" lacks antecedent basis. However, MPEP 2173.05(e) indicates that a lack of antecedent basis applies when a phrase is unclear. Applicants respectfully contend that the phrase "multiplicity of stains" is not unclear, because the preceding claims do not exclude the use of a multiplicity of stains. Nevertheless, Applicants have amended claim 1 to explicitly recite using a multiplicity of stain, and thus respectfully contend that dependent claim 6 is not indefinite. Applicants therefore respectfully request that this ground of rejection be withdrawn.

2. Claim Rejections - 35 USC §112, first paragraph, Enablement

Claims 1, 2, and 4-6 stand rejected under 35 USC §112 as failing to comply with the enablement requirement, based on the following reasoning: (1) there is no correlation between TGF-β, p21, p16, and p27 and the states of apoptosis, terminal differentiation, and senescence within a "tissue or cell sample" treated by a chemotherapeutic agent; (2) the term "chemopreventive" agents is not enabled; (3) and the specification does not teach the use of an antibody in staining SA-β-Gal.

Regarding the first reason for the enablement rejection, Applicants respectfully point out that the recited markers are used to determine an individual's response to cancer chemotherapy, which allows the determination of effectiveness in treating the individual, and not as markers to determine if cells are undergoing or have undergone apoptosis, terminal differentiation, or senescence. To avoid confusion about the focus of these claims, Applicants have deleted the phrase "associated with senescence, apoptosis or terminal differentiation" from the claims merely in order to expedite prosecution. Applicants submit that the claims are fully enabled for using SA-β-Gal,TGF-β, p21, p16, and p27 are used as markers to determine an individual's response to

a particular agent.

Regarding the second reason for the enablement rejection, Applicants note that the specification describes exemplary chemopreventive agents on page 7, line 27 ("...cytostatic differentiating agents such as retinoids..."). In addition, those of skill in the art readily recognize the term "chemopreventive," and numerous chemopreventive agents are known, such as anti-androgens, anti-estrogens, antioxidants, and several vitamins (see for example http://www.answers.com/topic/chemoprevention?method=5&linktext=Chemoprevention, visited April 25, 2006, which contains information from the Gale Encyclopedia of Cancer, 2002, The Gale Group, Inc). Consequently, the term "chemopreventive" is enabled.

Regarding the third reason for the enablement rejection, the claims have been amended to recite that the staining is accomplished using "either X-Gal, a detectably-labeled antibody directed against a biological marker, or both X-Gal and a detectably-labeled antibody directed against a biological marker, wherein said biological marker is p21, p27, p16, TGF-β or SA-β-Gal." The use of X-Gal for staining is described in Example 1 in the specification. Thus, the claims are enabled.

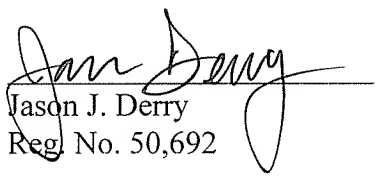
In view of the above discussion, Applicants submit that the claims as presented herein are enabled, and respectfully request that these grounds of rejection be withdrawn.

Conclusion

In view of the above amendments and remarks, the application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue. If there are any questions or comments regarding this Response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff LLP

Date: April 27, 2006

By: 
Jason J. Derry
Reg. No. 50,692

Phone: 312-913-0001
Fax: 312-913-0002